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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/571,146	07/17/2006	David Morton	4781075	3651
23280 7590 06/14/2011 Davidson, Davidson & Kappel, LLC 485 7th Avenue 14th Floor New York, NY 10018			EXAMINER ALSTRUM ACEVEDO, JAMES HENRY	
			ART UNIT 1616	PAPER NUMBER
			MAIL DATE 06/14/2011	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary**Application No.**

10/571,146

Applicant(s)

MORTON ET AL.

ExaminerJAMES H. ALSTRUM
ACEVEDO**Art Unit**

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 April 2011.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 3-17, 19-24, 27-33 and 35-42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3-17, 19-24, 27-33, and 35-42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB08)
Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claims 1, 3-17, 19-24, 27-33, and 35-42 are pending. Applicants' previously cancelled claims 25-26 and 34. Applicants newly cancelled claims 2 and 18. Applicants amended claims 1, 3, 5-6, and 19-20. Receipt and consideration of Applicants' amended claim set and remarks/arguments submitted on April 12, 2011 are acknowledged. All rejections/objections not explicitly maintained in the instant office action have been withdrawn per Applicants' claim amendments and/or persuasive arguments.

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Specification

The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re*

Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 5-8, 11-12, 16-20, 23-24, 27, and 35 remain rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 4, 16-19 and 21-22 of U.S. Patent No. 7,736,670 (U.S. Patent No. '670) (USPN '670). Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of recited claims claim methods of making particles comprising co-jet milling particles of active material with particles of additive material and both claim sets claim pharmaceutical compositions produced by said method. Independent claim 1 of the instant application is described above. Independent claim 1 of USPN '670 claims a method of making composite particles for use in a pharmaceutical composition for pulmonary administration comprising a milling step in which particles of active material are milled in the presence of particles of additive material, wherein the milling comprises one of three possibilities, including jet milling, and the additive material is dispersed over the active material (i.e. coated).

The primary difference between claim 1 of the instant application and claim 1 of USPN '670, is that USPN '670 recites different alternative milling procedures and recites that agglomerates of the particles of active and additive material are both broken up. These

differences nonetheless do not distinguish the claims of the instant application from the claims of USPN '670; because the claims of the instant application recite the same co-jet milling step as is contemplated by the claims of USPN '670 and would necessarily have the same or substantially similar result of breaking up agglomerates of active and/or additive particles. Regarding claim 35, because the claims of USPN '670 do not state that the jet milling is performed *in vacuo* or under inert conditions it is reasonable to conclude that the milling is done in the presence of air.

Regarding the recitation of different temperatures or pressures in the claims of the instant application, varying the temperature and pressure utilized during jet milling would be a routine modification of the jet-milling processes of USPN '670, absent the demonstration of the criticality of a particular temperature and/or pressure range or value. Concerning overlapping particle size ranges, a *prima facie* case of obviousness necessarily exists when the prior art range overlaps or touches a claimed range, such as in the instant rejection. MPEP § 2144.05. Thus an ordinary skilled artisan would have been motivated to experiment with the temperature and pressure utilized during the jet milling process of USPN '670 and would have had an expectation of successfully modifying the temperature and pressure used in said jet milling process. Therefore, a person of ordinary skill in the art at the time of the instant invention would have found claims 1, 5-8, 11-12, 16-20, 23-24, 27, and 35 *prima facie* obvious over claims 1, 4, 16-19 and 21-22 of U.S. Patent No. 7,736,670 (U.S. Patent No. '670) (USPN '670).

Response to Arguments

Applicants did not traverse this rejection and indicated they would consider the filing of a terminal disclaimer upon identification of allowable subject matter.

Claims 1-2, 5-8, 11-12, 16-24, 27, 35-36, and 39-40 remain provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 20, 33-35, 37, 39, 42-43, and 59-51 of copending Application No. 10/433,185 (copending '185).¹ Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of recited claims claim methods of making particles comprising co-jet milling particles of active material with particles of additive material and both claim sets claim pharmaceutical compositions produced by said method. Independent claim 1 of the instant application is described above. Independent claim 1 of copending '185 claims a method of preparing microparticles for use in a pharmaceutical composition for pulmonary administration comprising milling particles of active material are milled in the presence of particles of hydrophobic material (e.g. magnesium stearate or a phospholipid) material, wherein the milling comprises one of three possibilities, including jet milling, and the hydrophobic material is dispersed over the active material (i.e. coated).

The primary difference between claim 1 of the instant application and claim 1 of copending '185, is that copending '185 recites different alternative milling procedures and recites that agglomerates of the particles of both active and hydrophobic material are broken up, and the resulting microparticles exhibit delayed dissolution of the active substance. These differences nonetheless do not distinguish the claims of the instant application from the claims of copending '185; because the claims of the instant application recite the same co-jet milling step as is contemplated by the claims of copending '185 and would necessarily have the same or substantially similar result of breaking up agglomerates of active and/or additive particles.

¹ Application No. 10/433,185 was allowed on May 16, 2011. This rejection will become non-provisional once

Regarding claim 35, because the claims of copending '185 do not state that the jet milling is performed *in vacuo* or under inert conditions it is reasonable to conclude that the milling is done in the presence of air. Regarding the recitation of different temperatures or pressures in the claims of the instant application, varying the temperature and pressure utilized during jet milling would be a routine modification of the jet-milling processes of copending '185, absent the demonstration of the criticality of a particular temperature and/or pressure range or value. Concerning overlapping particle size ranges, a *prima facie* case of obviousness necessarily exists when the prior art range overlaps or touches a claimed range, such as in the instant rejection. MPEP § 2144.05. Thus an ordinary skilled artisan would have been motivated to experiment with the temperature and pressure utilized during the jet milling process of copending '185 and would have had an expectation of successfully modifying the temperature and pressure used in said jet milling process. Therefore, a person of ordinary skill in the art at the time of the instant invention would have found claims 1-2, 5-8, 11-12, 16-24, 27, 35-36, and 39-40 *prima facie* obvious over 20, 33-35, 37, 39, 42-43, and 59-51 of copending Application No. 10/433,185 (copending '185).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

Applicants did not traverse this rejection and indicated they would consider the filing of a terminal disclaimer upon identification of allowable subject matter.

Claims 1-2, 5, 7-8, 11-12, 16-17, 21-22, 27, 29-33, 35, and 41-42 remain provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 9 of copending Application No. 10/552,326 (copending '326) (US filing date of March 9, 2006). Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of recited claims claim methods of making particles comprising co-jet milling particles of active material with particles of additive material and both claim sets claim pharmaceutical compositions produced by said method. Independent claim 1 of the instant application is described above. Dependent claim 9 of copending '326 claims a passive dry powder inhaler device comprising a dry powder formulation comprising (i) apomorphine and a metal stearate, wherein upon actuation of the device, a dosing efficiency at 5 microns of at least 70% is achieved, and wherein the composite active particles of the pharmaceutical composition are prepared by jet milling apomorphine particles (i.e. active particles) in the presence of metal stearate additive material. Claim 9 of copending '326 anticipates claims 1-2, 5, 16, 29, and 33 of the instant application.

Regarding the remaining claims of the instant application, these claims are an obvious modification of claim 9 of copending '326 as articulated below. The differences between the remaining claims of the instant application and claim 9 of copending '326 is that copending '326 explicitly recites an overlapping particles size and/or dosing efficiency. Regarding claim 35, because the claim 9 of copending '326 does not state that the jet milling is performed *in vacuo* or under inert conditions it is reasonable to conclude that the milling is done in the presence of air.

Regarding the recitation of different temperatures or pressures in the claims of the instant application, varying the temperature and pressure utilized during jet milling would be a routine

modification of the jet-milling processes recited in claim 9 of copending '326, absent the demonstration of the criticality of a particular temperature and/or pressure range or value. Concerning overlapping particle size ranges, a *prima facie* case of obviousness necessarily exists when the prior art range overlaps or touches a claimed range, such as in the instant rejection. MPEP § 2144.05. Thus an ordinary skilled artisan would have been motivated to experiment with the temperature and pressure utilized during the jet milling process of copending '326 and would have had an expectation of successfully modifying the temperature and pressure used in said jet milling process. Therefore, a person of ordinary skill in the art at the time of the instant invention would have found claims 1-2, 5, 2-8, 11-12, 16-17, 21-22, 27, 29-33, 35, and 41-42 *prima facie* obvious over claim 9 of copending Application No. 10/552,326 (copending '326).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

Applicants did not traverse this rejection and indicated they would consider the filing of a terminal disclaimer upon identification of allowable subject matter.

Claims 1-12, 16-24, 29-32, 35-36, and 39-42 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 4, 6, 12, 15-22, 26, 30, and 39-40 of copending Application No. 11/791,670 (copending '670). Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of recited claims claim methods of making particles comprising co-jet milling

particles of active material with particles of additive material and both claim sets claim pharmaceutical compositions produced by said method. Independent claim 1 of the instant application is described above. Independent claim 15 of copending '670 claims a method of preparing a pharmaceutical formulation comprising fusing an additive material (i.e. dispersing agent) to the surface of solid pharmaceutically active particles and admixing with a liquefied propellant gas.

Independent claim 15 of copending '670 does not explicitly recite jet-milling or that the dispersing agent coats the active agent particles. It is the Examiner's position that the fusing step is equivalent to milling, as evidenced by dependent claim 17 of copending '670, which recites that mechanical energy is applied to contact the dispersing agent and particles of active agent and fuse these components together. Regarding the recitation that the additive particles coat the active particles, it is the Examiner's position that the fusing step of copending '670 necessarily coats the additive material onto the active particles, as evidenced, for example, by dependent claim 19 of copending '670, which explicitly states that the dispersing agent at least partially coats the active agent. It is the Examiner's position that the ordinary skilled artisan would readily recognize jet milling as a conventional technique used to obtain fine particulate compositions that necessarily utilizes the application of mechanical energy. Regarding the properties (e.g. FPF) recited in Applicants' dependent claims, it is the Examiner's position that these properties are necessarily present in the particulate formulations claimed or made by the claimed processes of copending '670. Therefore, a person of ordinary skill in the art at the time of the instant invention would have found claims 1-12, 16-24, 29-32, 35-36, and 39-42 *prima*

facie obvious over claims 1, 4, 6, 12, 15-22, 26, 30, and 39-40 of copending Application No. 11/791,670 (copending '670).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

Applicants did not traverse this rejection and indicated they would consider the filing of a terminal disclaimer upon identification of allowable subject matter.

Claims 16-18, 21-24, and 27-33 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 35, 38, 41-43, and 45 of copending Application No. 12/767,530 (copending '530).² Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of recited claims claim methods of making particles comprising co-jet milling particles of active material with particles of additive material and both claim sets claim pharmaceutical compositions produced by said method. Independent claim 1 of the instant application is described above. Independent claim 1 of copending '530 claims composite active particles for use in a pharmaceutical composition for pulmonary administration comprising particles of active material with particles of additive material on the surface of the active particles, wherein the composite particles have a MMAD of 10 microns or less.

² Copending '530 was filed on March 17, 2010.

The primary difference between independent claim 35 of copending '530 and the rejected composition claims of the instant application is that the claims of copending '530 do not recite that the additive material is present as a coating on the surface of the active particles. This difference is not material, because for the additive particles of the instant application to contain a coating of additive material that additive material must be on the surface of the active particles as is recited in the claims of copending '530. The dependent claims of copending '530 and the instant application recite the same or substantially similar limitations. Regarding particle size, the claims of copending '530 recite particle size ranges that overlap with the ranges recited in the rejected claims of the instant application. A *prima facie* case of obviousness necessarily exists when the prior art range overlaps or touches a claimed range, such as in the instant rejection. MPEP § 2144.05.

Regarding the recited properties (e.g. FPF) of the claimed compositions, it is the Examiner's position that these properties are necessarily present in the particulate formulations claimed in copending '530. Regarding dependent claim 33 of the instant application, it is a *prima facie* obvious modification of the claimed particles/compositions of copending '530 to place said particles/compositions into a dry powder inhaler, as evidenced by dependent claim 45 of copending '530, which explicitly suggests the placement of said particles/compositions in a DPI. Therefore, a person of ordinary skill in the art at the time of the instant invention would have found claims 16-18, 21-24, and 27-33 *prima facie* obvious over claims 25, 38, 41-43, and 45 of copending Application No. 12/767,530 (copending '530).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

Applicants did not traverse this rejection and indicated they would consider the filing of a terminal disclaimer upon identification of allowable subject matter.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Claims 1-24, 27-33, and 35-42 are rejected. Claim 18 is objected. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James H. Alstrum-Acevedo whose telephone number is (571) 272-5548. The examiner can normally be reached on M-F, ~10:00-6:00 and Saturdays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on (571) 272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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